DEC 2 0 2000

Trimedyne

K002308

ATTACHMENT I

510(k) Summary of Safety and Effectiveness Information
Trimedyne® Holmium Laser System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information: Trimedyne, Inc.
P.O. Box 57001
Irvine, CA 92619-7001

Contact person: Susan H. Gamble
Vice President, Regulatory Affairs and Quality

Summary Date: November 6, 2000

II. Device Name

Proprietary: Trimedyne Holmium Laser System, including:

- Trimedyne OmniPulse™ Holmium Laser System (Model 1210)
- Trimedyne OmniPulse™-MAX Holmium Laser System (Model 1210-VHP)
- Model 1500-A Holmium Laser System

Common: Holmium:Yttrium Aluminum Garnet (Holmium:YAG) Laser

Classification: Laser-Powered Instrument

III. Predicate Device

1. Coherent Modified VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers.
2. Ximed Medical/Prosurg Electrodes/Probes.
3. Trimedyne Optilase Model 1000-100 Nd:YAG Laser System.

IV. Device Description

The Trimedyne Holmium Laser System is a medical grade, Class IV, pulsed, solid state Holmium:YAG laser system designed to deliver pulsed infrared laser energy with a wavelength of 2.1 μm and up to 350 microseconds pulsewidth. Menu-driven control options allow the users to select pulse repetition rate, output energy, and lasing duration.

TRIMEDYNE, INC.
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V. Intended Use

The Trimedyne Holmium:YAG Laser System is intended for incision, excision, resection, ablation, vaporization, coagulation, and hemostasis in multispecialty applications, including dermatology and plastic surgery, gastroenterological/ gastrointestinal surgery, general surgery, genitourinary/urology surgery (including Holmium laser incision, excision, resection, ablation, hemostasis, vaporization, and enucleation in the treatment of benign prostatic hyperplasia), gynecological surgery, lithotripsy and percutaneous urinary lithotripsy, orthopedic surgery, otorhinolaryngology surgery, and percutaneous lumbar discectomy.

VI. Technological Characteristics

The laser system is a Holmium:YAG laser which emits light at a wavelength of 2.1 μm (near infrared) and a maximum pulsewidth of 350 microseconds. The laser has the capability of attaining a maximum output of 100 watts of power.

VII. Non-clinical and Clinical Data

The non-clinical and clinical study data were included in this premarket notification to demonstrate that the Trimedyne Holmium Laser Systems are safe and effective for the treatment of benign prostatic hyperplasia.

VIII. Conclusion

The Trimedyne Holmium:YAG Laser System is substantially equivalent to the three predicate devices described in this premarket notification. Furthermore, the non-clinical and clinical data submitted demonstrated the safety and effectiveness of the device for the treatment of BPH. Therefore, upon clearance of this submission, the Trimedyne Holmium:YAG Laser System will be marketed for the proposed expanded indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Ms. Susan H. Gamble
Vice President, Regulatory Affairs
and Quality
Trimedyne, Inc.
P.O. Box 57001
Irvine, California 92619-7001

Re: K002308
Trade Name: OmniPulse™ Holmium Laser System, Model 1210
OmniPulse™ MAX Holmium Laser System, Model 1210-VHP
Model 1500-A Holmium Laser System
Regulatory Class: II
Product Code: GEX
Dated: November 6, 2000
Received: November 7, 2000

Dear Ms. Gamble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002308

Device Name: **Trimedyne Holmium Laser System**, including:

OmniPulse™ Holmium Laser System, Model 1210
OmniPulse™-MAX Holmium Laser System, Model 1210-VHP
Model 1500-A Holmium Laser System

Indications for Use:

Incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

1. **Dermatology and Plastic Surgery** of soft, mucosal, fatty, and cartilaginous tissues, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including:

- scars
- tattoo removal
- vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea)
- corns
- papillomas
- basal cell carcinomas
- lesions of skin and subcutaneous tissue
- plantar warts
- periungual and subungual warts
- debridement of decubitus ulcer
- skin tag vaporization

(Continued on next page)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use ✓ OR Over-the-Counter Use _____

Indications - continued

2. **Gastroenterological/Gastrointestinal Surgery**, including:

- cholecystectomy
- lysis of adhesions
- appendectomy
- biopsy
- pylorostenotomy
- benign and malignant lesions
- rectal polyps of sigmoid colon
- gall bladder calculi
- biliary/bile duct calculi
- benign and malignant neoplasm
- polyps
- colitis
- ulcers
- angiodysplasia
- hemorrhoids
- varices
- esophagitis
- esophageal ulcer
- Mallory-Weiss tear
- gastric ulcer
- duodenal ulcer
- non-bleeding ulcer
- gastric erosions
- colorectal cancer
- gastritis
- bleeding tumors
- pancreatitis
- vascular malformations
- telangiectasias
- telangiectasias of the Osler-Weber-Rendu disease

3. **General Surgery** of soft tissues, including:

- skin incision
- tissue dissection
- exeision of external tumors and lesions
- complete or partial resection of internal organs
- tumors or lesions
- tissue ablation
- mastectomy
- hepatectomy
- pancreatectomy
- splenectomy
- thyroidectomy
- parathyroidectomy
- herniorrhaphy
- tonsillectomy
- lymphadenectomy
- partial nephrectomy
- pilonidal cystectomy
- resection of lipoma
- pelvic adhesiolysis
- debridement of decubitus ulcer
- hemorrhoids
- pilodidal cyst removal and repair
- debridement of statis ulcer
- biopsy

4. **Genitourinary Surgery/Urology**, including:

- superficial urinary bladder tumors
- invasive bladder carcinoma
- urethral strictures
- lesions of the external genitalia
- bladder
- urethral and ureteral tumors
- condylomas
- urethral and penile hemangioma
- bladder neck obstructions
- holmium laser incision, excision, resection, ablation, hemostasis, vaporization, and enucleation in the treatment of benign prostatic hyperplasia

5. **Gynecological Surgery** during open and endoscopic procedures, including:

- condyloma acuminata

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Indications - continued

6. **Lithotripsy and Percutaneous Urinary Lithotripsy**, including:

- fragmentation of urinary calculi
- fragmentation of urethral calculi
- fragmentation of kidney calculi
- treatment of distal impacted fragment of steinstrasse when guide wires cannot be passed

7. **Orthopedic Surgery** in pathological soft and cartilaginous tissue in small and large joints, including:

- knee meniscectomy
- knee synovectomy
- chondromalacia and tears
- loose body debridement
- lateral retinacular release
- debridement of the degenerative knee
- plica removal
- ligament and tendon release
- contouring and sculpting of articular surfaces
- debridement of inflamed synovial tissue
- capsulectomy in the knee
- chondroplasty in the knee
- chondromalacia ablation

8. **Otorhinolaryngology (ENT) Surgery** in soft, mucosal, cartilaginous and bony tissue, including:

- endosinus surgery
- functional endoscopic sinus surgery
- turbinate procedures (e.g.. turbinectomy)
- dacryocystorhinostomy (DCR)
- ethmoidectomy
- polypectomy
- maxillary antrostomy
- frontal sinusotomy
- sphenoidotomy

9. **Percutaneous Lumbar Discectomy** in soft, cartilaginous, and bony tissue, including:

- foraminoplasty

Ann for CMW

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